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10/534,930

12/22/2005

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EXAMINER

PATEL, TARLA R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/534,930 | Applicant(s) CAREY, MARCUS PATRICK | |
| | Examiner TARLA R. PATEL | Art Unit 3772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15,33,34 and 43-48 is/are pending in the application.
- 4a) Of the above claim(s) 33 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15,34 and 43-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claim 45 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups and Species. Further, after review of claim 45 is also withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to a nonelected Species. With respect to claim 45, it recites the limitations requiring the membrane is twin walled and is inflatable; therefore it is also directed to the non-elected species (d).

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 9/29/08. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the positioning a second reinforcing material over the exposed fascia of the posterior vaginal wall and re-fixing the vaginal epithelium over the second reinforcing material and the fascia of the posterior vaginal wall must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The applicant submitted an amended abstract on 12/16/08 has been acknowledged and OK to enter.

Claim Objections

5. Claim 33 is objected to because of the following informalities: the claim 33 has been withdrawn by the applicant, however, still applicant is required to present claim

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recitation of claim subject matter of claim 33 as being withdrawn, and the applicant has removed the claim language of the claim 33 only presenting status identifier to the claim. Appropriate correction is required.

6. Claim 42 is objected to because of the following informalities: the claim 42 has been cancelled previously, therefore, it has not been considered on merit. The applicant is advised to refer to originally filed claims 1-42 was pending on 5/13/05; the claim 42 was cancelled by restriction requirement. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claim 12 recites the limitation "the positioning a second reinforcing material over the exposed fascia of the posterior vaginal wall and re-fixing the vaginal epithelium over the second reinforcing material and the fascia of the posterior vaginal wall" in claim is not clear to the examiner what structure is second reinforcing material and how it is positioned and re-fixed in vaginal epithelium over the second reinforcing material. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 1-15, 34 and 43-48 rejected under 35 U.S.C. 103(a) as being unpatentable over Kovac (6,599,235) in view of Rosenblatt et al. (6,981,983).

Kovac discloses a method for repairing a vaginal wall which has been damaged by one or more prolapsed pelvic organs (column 3 lines 36-42) method comprising mobilizing the vaginal epithelium off the underlying fascia of at least a portion of the damaged vaginal wall (see figure 4-9), positioning a reinforcing material (29) over the exposed fascia (see figure 4-9), re-fixing the vaginal epithelium over the reinforcing material and the fascia (see figure 4-9 and column 7 line 52-column 8 line 10).

With respect to claims 2-3, Kovac obviously discloses the vaginal wall being repaired is the anterior vaginal wall and the vaginal epithelium is mobilized off the underlying fascia by incision and lateral dissection through the arcus tendineous fascia pelvis and continued towards the sacrospinous ligaments on both sides and into the paravaginal space on each side of the anterior vaginal wall (see figure 4-9).

With respect to claim 4, Rosenblatt et al. obviously discloses the reinforcing material (29) is a synthetic mesh having laterally extending arms on both sides and the mesh is positioned over the exposed fascia of the anterior vaginal wall with each lateral arm of the mesh placed into tunnels extending from the anterior vaginal wall dissection into the paravaginal spaces (see figure 4-9) and (column 7 line 52 and column 9 line 34).

With respect to claim 5, Kovac the vaginal wall being repaired is the posterior wall of the vagina and the vaginal epithelium is mobilized off the underlying fascia by incision and dissection laterally to the levator ani muscles on each side and in the upper part of the vagina in a lateral and cranial direction through the rectal pillars on both sides towards

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the sacrospinous ligaments on each side of the vaginal wall (see figure 4-9) and (column 7 line 52 and column 9 line 34).

With respect to claim 6, Kovac obviously discloses the reinforcing material (29) is a synthetic mesh having upwardly extending arms on both sides and the mesh is positioned over the exposed fascia of the posterior vaginal wall with each upwardly extending arm of the mesh placed into tunnels extending from the posterior vaginal wall dissection to the respective sacrospinous ligament (see figure 4-9) and (column 7 line 52 and column 9 line 34).

With respect to claims 7-9 and 13, Kovac discloses reinforcing material once positioned over the exposed fascia of the vaginal wall being repaired is thereafter attached to the underlying fascia by sutures (column 7 line 52 and column 9 line 34) and the fascia of the damaged vaginal wall is plicated after the vaginal epithelium has been mobilized but prior to the positioning of a reinforcing material over the exposed fascia (column 7 line 52 and column 9 line 34).

However, Kovac does not disclose locating an intra-vaginal splint into the vagina and the intra-vaginal splint remains located within the range for a period of at least three weeks and between 4 to 6 weeks following location within the vagina and the intra-vaginal splint includes two longitudinally extending side arms both having first and second ends, side arms being connected at their respective first ends by a first connecting member and at their respective second ends by a second connecting member, wherein first and second connecting members are of different lengths, the intra-vaginal splint is substantially trapezium shaped, at least part of the interior area is

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closed by a membrane and first connecting member and second connecting member disposed respectively first and second plane and these planes are at an angle, angle is in the range from about 8 to 15 degrees and is about 10 degrees.

However, Rosenblatt et al. discloses an intra-vaginal splint into the vagina (see figure 25D) and the intra-vaginal splint remains located within the range for a period of at least three weeks and between 4 to 6 weeks following location within the vagina (as disclosed in column 3 lines 31-36 discloses that the system to hold intact soft tissue structures together would provide a repair of sufficient duration is interpreted as having splint remaining located in the vagina for a period of at least 3 weeks and between 4 to 6 weeks to fully repair the vagina) and the intra-vaginal splint (600) includes two longitudinally extending side arms (630) both having first and second ends (as shown in figure 25C side arm having top end as first end and bottom end as second end), side arms being connected at their respective first ends by a first connecting member (604) and at their respective second ends by a second connecting member (602), wherein first and second connecting members are of different lengths (see figure 25C) the intra-vaginal splint is substantially trapezium shaped (as disclosed in column 21 lines 5-12, that these element may be provided any size and shape is broadly interpreted as having trapezium shape), at least part of the interior area is closed by a membrane and first connecting member and second connecting member disposed respectively first and second plane (see figure 25C) and these planes are at an angle (as disclosed in column 21 lines 5-12, that these element may be provided any size and shape is broadly interpreted as planes are having an angle), angle is in the range from about 8 to 15

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degrees and is about 10 degrees. At the time of the invention was made, it would have been obvious to one having ordinary skill in the art to locating the splint into the vagina wall with method of Kovac to repair vagina wall, as taught by Rosenblatt et al. to hold intact soft tissue structure together would provide sufficient force to hold the intact structure together.

Response to Arguments

10. Applicant's arguments with respect to claims 1-15, 33, 34 and 43-48 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARLA R. PATEL whose telephone number is (571)272-3143. The examiner can normally be reached on M-T 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tarla R Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772